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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LIU, SAMUEL W	
ART UNIT	**PAPER NUMBER**
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/782,953	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Samuel W. Liu	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *59,61,62 and 70* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *59,61,62 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

Claims 59, 61-62 and 70 are pending.

The amendment filed 5/31/07 which amends claims 59 and 61-62, and cancels claims 1-58, 60, 63-69 and 71-101 has been entered. The applicants' request (filed 5/31/07) for extension of time of three months has been entered. Claims 59, 61-62 and 70 are examined in this Office action.

Withdrawal of the rejections

- The rejection under 35 USC 102 of claims 59, 62 and 70 by Sussman et al. is withdrawn in light of that the applicants' argument with regard to the "human" subject is persuasive.

- The rejection under 35 USC 103 of claims 59, 61 and 62 by Chin et al. is withdrawn in light of that the applicants' argument with regard to the inherency of the MCIP's relation to calcineurin referring to pages 7-8 of the response filed 5/21/07 is persuasive.

Maintained -Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 70 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 70 recitation "second pharmaceutical agent" is unclear whether or not it refers to the "small molecule" set forth in claim 59 for a second administration, or otherwise molecule or agent different from said "small molecule".

The applicants' response to the rejection under 35 USC112, second paragraph

At bridging pages 4-5, the response filed 5/31/07 argues that one skilled in the art would recognize that the "second pharmaceutical agent" differs from the "small molecule' of claim 59; and thus, infers that the claim is not indefinite.

The applicants' argument is found unpersuasive because it ambiguously refers to (i) the same molecule set forth in claim 59 but is used for the second administration, or (ii) a molecule differing from the "small molecule" of claim 59. Thus, claim 7 is indefinite. Therefore, the rejection is maintained.

Maintained-Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C.

122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 59, 61 and 70 remain rejected under 35 U.S.C. 102(b) as being anticipated by Cavazza C. (US Pat. No. 4330557).

In the patent claim 1, Cavazza teaches administering to human the level of fatty acid, e.g., oleic acid or linoleic acid which is known to be a calcineurin activator, i.e., an agonist. Since calcineurin is well known a regulator for muscle growth/differentiation, said agonist of calcineurin must have the inherent ability of regulating muscle growth/differentiation. Thus, administering the agonist of calcineurin necessarily leads to modulating muscle cell growth. Therefore, Cavazza teaches the method of claims 59 and 61.

On col. 3, lines 15-19, Cavazza teaches co-administering acyl-carnitine in order to minimize the depletion of endogenous carnitine in muscular tissues, particular in the myocardium, which anticipates claim 70.

* Note that the disclosed method is directed to regulating muscle cell growth but not the MCIP's expression itself which is considered to be a molecular mechanistic step of the regulation, and that, since MCIP1 gene expression is strongly up-regulated by calcineurin (see "*Discussion of art*"), any calcineurin agonist must have the inherent property of modulating MCIP1 protein expression, and thereby modulating the muscle cell growth. Therefore, Cavazza's reference teaches instant step (b) of claim 59.

Claims 59 and 62 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lanza et al. (US Pat. No. 5651980).

In patent claims 22-23, Lanza et al. teach a method of administering a drug, e.g., cyclosporin A, to an animal. In patent claim 4, Lanza et al. teach that said animal is human. Since calcineurin is well known a regulator for muscle growth/differentiation, and since cyclosporin A inhibits calcineurin activity, cyclosporin A is considered to be an antagonist of muscle cell growth. Thus, administration of cyclosporin A necessarily leads to regulating the muscle cell growth. Therefore, Lanza et al. anticipate claims 59 and 62.

* Note that the disclosed method is directed to regulating muscle cell growth but not the MCIP's expression itself which is considered to be a molecular mechanistic step of the regulation, and that, since MCIP1 gene expression is strongly up-regulated by calcineurin (see "*Discussion of art*"), any molecule/agent selected such as, herein, cyclosporin A which is antagonist of calcineurin has an inherent property of involving in modulation of MCIP1 protein expression, and thereby modulating the muscle cell growth. Therefore, the Lanza et al. dereference inherently teaches instant step (b) of claim 59.

Claims 59, 62 and 70 remain rejected under 35 U.S.C. 102(b) as being anticipated by Selawry et al. (US Pat. No.5958404).

In patent claims 1-2 and 12-13, Selawry et al. teach a method of treating a disease state in human comprising administering a drug, e.g., cyclosporin A (claims 12-13) to human (claim 2). Since calcineurin is well-known a regulator for muscle growth/differentiation, and since cyclosporin A has the inherent property of involving in modulation of MCIP protein expression (see the above discussion), administration of cyclosporin A necessarily leads to regulating muscle cell growth. Therefore, Selawry et al. anticipate the method of claims 59 and 62.

In patent claim 1, Selawry et al. teach that the method further comprises administering to human sertoli cells which produce biological factor (claim 6), e.g., hormone (claim 3), wherein said biological factor is considered to be a pharmaceutical agent, which anticipate claim 70.

The applicants' response to the rejection under 35 USC 103(a)

At pages 5-7, the response filed 5/31/07 argues that since applicants have amended claims to more precisely state that the small molecule is selected on the basis of it's MCIP modulation function (referring to the amended step (b) of claim 59), the cited 102 references fail to teach the claimed method. The response stresses that the knowledge that calcineurin regulates MCIP can only be found in the applicants' specification. Thus, the response infers that the rejection is improper.

The applicants' arguments are found unpersuasive because of the reasons stated above and the reasons below. The claims are directed to a method of regulating muscle cell growth comprising steps *a*, *b*, and *c* wherein step *c* is considered to be a molecular mechanistic step of said regulation of muscle cell growth. In addition to teaching the limitations of steps *a* and *b*, all three 102 references inherently teach step *b*. This is because MCIP1 gene expression is strongly up-regulated by calcineurin (see "*Discussion of art*"), and because any agonist or antagonist of calcineurin must have the inherent property of modulating the MCIP1 expression due to ability of calcineurin to regulate the MCIP1 gene expression. In other word, the calcineurin agonist taught by Cavazza, and the calcineurin antagonist taught by Lanza et al. and Selawry et al. must be involved in regulating the MCIP1 gene expression and thereby modulating muscle cell growth in a subject when said calcineurin agonist or the antagonist is administered to the subject thereof.

The applicants' discussion regarding that the knowledge of calcineurin regulation of the MCIP1 expression is only provided by instant specification provides an additional support for the inherency discussed above. Thus, the above 102 rejections are deemed proper; and therefore, the rejections are maintained.

Conclusion

No claims are allowed.

Discussion of the art

The prior art made of record and not currently relied upon in any rejections is considered pertinent to Applicants' disclosure:

• Hilioti et al. (*Gene Dev.* (2003) 18, 35-47) teach that MCIP1 gene expression is strongly up-regulated by calcineurin signaling (page 36, left column, 2nd paragraph).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon, can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

Samuel Wei Liu, Ph.D.

Patent Examiner, Art Unit 1656

July 25, 2007